New Technologies

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Objectives

• Review current, evolving, and emerging coronary interventional and structural heart technologies and their relevant clinical applications performed in both the cardiac catheterization lab and hybrid OR settings
Percutaneous Coronary Intervention (PCI)

- Most frequently performed therapeutic procedure in medicine
- Encompasses PTCA, Atherectomy, and Stent implantation
- Utilized in treatment of both Chronic Stable Angina and Acute Coronary Syndromes (ACS)
- ~1 million PCI’s performed annually in U.S.
Concept

- First PTCA performed in 1977
- Acute limitations include vessel dissection, thrombosis, and elastic recoil resulting in abrupt vessel closure
- Long term limitations include constrictive remodeling, neointimal hyperplasia, angiographic restenosis, and need for target lesion revascularization (TLR)

- BMS addressed issue of abrupt vessel closure and negative remodeling
- DES release of antiproliferative agent reduced incidence of in-stent restenosis and TLR
- Increased risk of late and very late stent thrombosis
- Associated with high morbidity and mortality
Components (PCI)

- **Platform**
  - Stainless steel
  - Cobalt or Platinum chromium

- **Polymer**
  - Durable and permanent
  - Biocompatible

- **Antiproliferative Drug**
  - Sirolimus and Paclitaxel
  - Everolimus and Zotarolimus

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Concept

- **Issue was inflammation and fibrin deposition of uncovered stent struts**
  - Impaired endothelialization
  - Delayed hypersensitivity reaction leading to late acquired incomplete stent apposition from positive remodeling
  - Thrombus dissolution

- **Neoatherosclerosis**
Evolution

Advantages
- Deliverability
- Flexibility
- Conformability
- Less injury/better healing
- Thromboresistant polymer
- Drug kinetics
- Less target lesion failure

Limitations
- Longitudinal deformation
- Stent fracture
- Permanency (stent & polymer)
- Altered vasomotion
- Neoatherosclerosis
- DAPT duration

Current Generation DES

Antiproliferative drug
- Paclitaxel

Stent material
- SES
- BES
- EES
- NES

Polymer type (μm)
- 22
- 18
- 10
- 6
- 5
- 3
- 1

Biodegradable-Polymer material
- PDLLA
- PLLA
- PLA
- PLLA/PLGA
- PLGA
- PDLLA-PCL

Covering distribution
- Circumferential
- Abdominal

Platform material and strut thickness (μm)
- Taxus
- Cypher
- BioMatrix

Early-generation DES
- Biodegradable polymer DES
- Durable polymer
- Biodegradable polymer
- Stainless steel
- Cobalt-chromium or platinum-chromium

Heart Institute at UPMC Hamot
PCI

- Drug-Coated Balloon
- Polymer-Free Drug-Coated Stent
- Biodegradable Polymer Stent
- Bioresorbable Vascular Scaffold
- Atherectomy
- iFR

Drug Coated Balloon (DCB)

- Non stent-based local delivery of antiproliferative agent (Paclitaxel)
- First coronary application in ISR lesions in 2003
- 9 different coronary DCBs with CE Mark approval in Europe
- Advantageous in ISR to avoid multiple stent layers or when prolonged DAPT not desirable
- Disadvantage is absence of stent scaffold
**Polymer-Free Drug-Coated Stent**

- Drug is eluted directly from metallic platform without need for polymeric drug carrier
- Drug transferred into vessel wall over period of one month
- Potential to provide the efficacy advantage of DES with shortened DAPT regimen

**Biodegradable Polymer Stent**

- Thin-strut metal platform with an abluminal polymer
- Engineered to completely degrade in months (~4)
- Rate and profile of drug release fine-tuned by polymer degradation (3 months)
- (theoretical) shorten length of exposure to polymer and decrease late/very late stent thrombosis
Bioresorbable Vascular Scaffold (BVS)

**Objectives**
- Function as vessel scaffold comparable to metallic stent
- Deliver therapeutic agent
- Leave no chronic foreign body implant
- Restore normal coronary artery structure and function
- Abolish need for prolonged DAPT
- Reduce late/very late stent thrombosis

**Advantages**
- Anatomic (ostial, bifurcation, restenotic lesions, stent overlap, strut fracture)
- Enables repeat same site treatments (PCI or CABG)
- Improve lesion imaging with CT or MRI (less artifact)
- Return of vessel geometry, compliance, and endothelial function
Atherectomy

- Coronary artery calcification increases complexity of PCI
- Inhibit stent delivery, risk of dissection, inadequate stent expansion/apposition associated with poor drug penetration
- Higher MACE rates
- Lesion modification and preparation prior to stenting alters plaque morphology and lesion compliance

Orbital Atherectomy

- Uses diamond-coated, eccentrically mounted burr that rotates over guidewire at 80-120,000 rpm
- Orbiting mechanism utilizes centrifugal forces to increase lumen diameter by differentially ablating calcium
- Easy setup, low procedural complication rates, and reduced restenosis
**Functional Coronary Assessment**

- More than half of patients have either no noninvasive ischemic evaluation or equivocal stress test findings prior to catheterization and/or revascularization
- Several limitations of coronary angiogram which produces 2-D representation of 3-D coronary lumen
- Despite discrepancy between angiographic severity and function, coronary angiogram still used in many cases as ultimate decision-maker
- FFR assists in making decisions about revascularization, balances risks and benefits of PCI, selects appropriate lesion for treatment, avoids unnecessary procedures, achieves reductions in medical costs, and improves clinical outcomes

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**Instantaneous Wave-Free Ratio (iFR)**

- Benefits include ability to obtain instantaneous lesion assessment without need to administer hyperemic agent
- Diagnostic accuracy similar to or better than that of FFR
- Noninferior to FFR-guided revascularization strategy with respect to MACE
- Potential to increase utilization due to improved patient tolerance
Mechanical Circulatory Support

- IABP
- Impella 2.5
- Impella CP
- TandemHeart
- Impella 5.0
- VA-ECMO
- Impella RP

Cardiogenic Shock

- Cardiac Output
  - reduced
- PCWP
  - Increased
- CVP/RAP
  - increased
- Blood Pressure
  - Low
- Systemic Vascular Resistance
  - Increased

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Mitral Valve Technology

- Mitral regurgitation (MR) is the most prevalent valvular heart disease in US
- Degenerative MR
  - Leaflet prolapse due to chordal elongation or rupture resulting in malcoaptation during ventricular contraction
- Functional MR
  - Distorted or dilated left ventricle displaces the papillary muscles resulting in failure of leaflets to coapt adequately

Mitral Valve Technology

- Approved 10/13 in patients with degenerative MR at prohibitive risk
- >2500 procedures performed in US in 2015
- 1 year mortality 2.2%, 92% had <2 MR after the procedure, and low rate of procedural complications
- Mean LOS <5 days, and <1% required reintervention

Anatomy of mitral valve

- Mitral valve apparatus:
  - Mitral valve Annulus.
  - Mitral leaflets with commissures.
  - Chordae tendinae.
  - Papillary muscles.
  - Supporting LV Wall.
  - Altogether called as mitral valve complex.
  - Resembles the Bishops “mitre”.

MitraClip

- Catheter-Based Mitral Valve Repair
- MitraClip® System

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**COAPT Trial**

![Trial design diagram]

- ~420 patients enrolled at up to 75 US sites
- Significant FMR (≥3+ by core lab)
- High risk for mitral valve surgery
- Specific valve anatomic criteria
- Randomize 1:1
  - MitraClip N=210
  - Control group Standard of care N=210

**Primary Endpoints**

- **Primary Effectiveness (min 1-year FU all pts)**
  - Recurrent heart failure hospitalizations
  - Superiority hypothesis (Andersen-Gill)
- **Primary Safety (1 year)**
  - Composite of all-cause death, stroke, worsening kidney function, or LVAD or cardiac transplant
  - Non-inferiority hypothesis

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**Mitral Valve Technology**

- **Indirect (via coronary sinus) and direct annuloplasty** (arterial transventricular and transseptal atrial approach)
- **Transcatheter mitral valve replacement (via transseptal or transapical approach)** in its early phases and not approved for sale in any country
• Patients with atrial fibrillation (AF) are at several-fold increased risk of thromboembolic events
• Current guidelines recommend lifelong oral anticoagulation for patients with annual stroke risk >2% (CHA2DS2-VASc)
• Patients may also be at risk for major bleeding (HASBLED) and/or require antiplatelet therapy for treatment of CAD/PCI
• 90% of thrombi originate from LAA
• Alternative treatment strategies led to development of interventional LAA occlusion

**Left Atrial Appendage (LAA) Closure**

**Watchman**

• Approved 3/15 for patients that are indicated for OAC, but have an appropriate reason to seek a nondrug alternative
• Largest registry to date showed implantation success rate >98%, and procedure- and device-related serious adverse event rate of 2.8%
• Viable alternative to long-term OAC in absence of MV stenosis
Parachute

• Scar from MI results in a cascade of events impairing both systolic and diastolic function of the heart
• Partitions and isolates damaged, nonfunctioning heart muscle from functioning segment
• Decreases overall volume and restores a more normal geometry and function in the left ventricle
• Results in both hemodynamic and functional improvement

Parachute

Mechanism of Action

The primary effect of the Parachute is improving diastolic compliance, which yields reduced end diastolic filling pressures and positive clinical results.

- Reduces wall stress in the upper chamber by changing LV geometry
- Reduces end diastolic filling pressures due to improved compliance
- Substitutes the stiff rigid scar with a more compliant Parachute that also provides outward force at the anchors to aid in diastolic filling